# Exhibit 26

# Corporate Compliance Quarterly Report to Board of Directors 3Q10

November 3, 2010

Bert Weinstein

Vice President, Corporate Compliance





# Office of Inspector General ON-SITE VISIT at Purdue AGENDA October 13-14, 2010

9:00 am - 9:30 am	Introductions and Tour

9:30 am – 10:45 am Overview of Purdue's Compliance Program, including the Compliance Department

10:45 am – Noon Overview of current products promoted by Purdue, promotional practices, and the

organization of Purdue's field sales force and others who perform Product Services Related

Functions

**Review of CIA Requirements** 

Code of Conduct processes

Training activities

Ineligible Persons screening

Noon – 1:00 pm Lunch

1:00 pm - 3:00 pm Review of CIA Requirements (continued)

- Disclosure program processes and log, including reported matters and disciplinary actions

Medical Services and Product Inquiries Database

Promotional Monitoring Program

- Ongoing investigations/legal proceedings

Reportable Events

- Fee-For-Service and all other contractual arrangements with Health Care Providers

 Non-Promotional Educational Sponsorship Activities, Medical Liaisons & Informational Activities

- Charitable grants and sponsorships

- Materials

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3:00 pm - 5:00 pm

### OIG ON-SITE VISIT AGENDA October 13-14, 2010

9:00 am - 10:45 am - Follow-up Items from October 13, 2010

- IRO Reviews

10:45 am – 11:00 am Break for OCIG Conference

11:00 am – 1:00 pm Employee Interviews (with 8-10 employees)

1:00 pm – 1:15 pm Break for OCIG Conference

1:15 pm – 2:15 pm Lunch

2:15 pm – 2:45 pm Site visit close-out meeting with Compliance Officer

2:45 pm – 3:15 pm Break for OCIG Conference

3:15 pm – 3:45 pm Site visit close-out meeting with Purdue





### Introduction to Purdue

- The actions that led to the imposition of Purdue's CIA occurred during a time of rapid growth for a small, privately held company. Subsequently, due to a number of patent challenges, Purdue's employee population was reduced to 1200 employees
- Since 2006 Purdue has gradually grown. Purdue recently introduced both Ryzolt and a re-formulation of OxyContin, and has received FDA approval for Butrans, a 7-day transdermal pain medication
- Our focus is on responsibility and leadership in pain management, advocacy and treatment options
- We are proud to share our compliance program with OIG





# Purdue Corporate Compliance

- In March 2004, we hired Bert Weinstein as Vice President, Corporate Compliance, and created the new Corporate Compliance Department. (Prior to 2004, compliance initiatives were led by Purdue's Law department.)
- Bert was a founder in 1999 and Co-Chair for seven years of the Pharmaceutical Compliance Forum, our industry's organization of compliance professionals. Bert is a recognized and active leader in the compliance field.
- Bert is a member of Purdue's Executive Committee; reports to both the President & CEO, and the Board of Directors
- This formal organizational structure, and the important relations it establishes at Purdue, have been important to our success with compliance



# Purdue's Compliance Charter

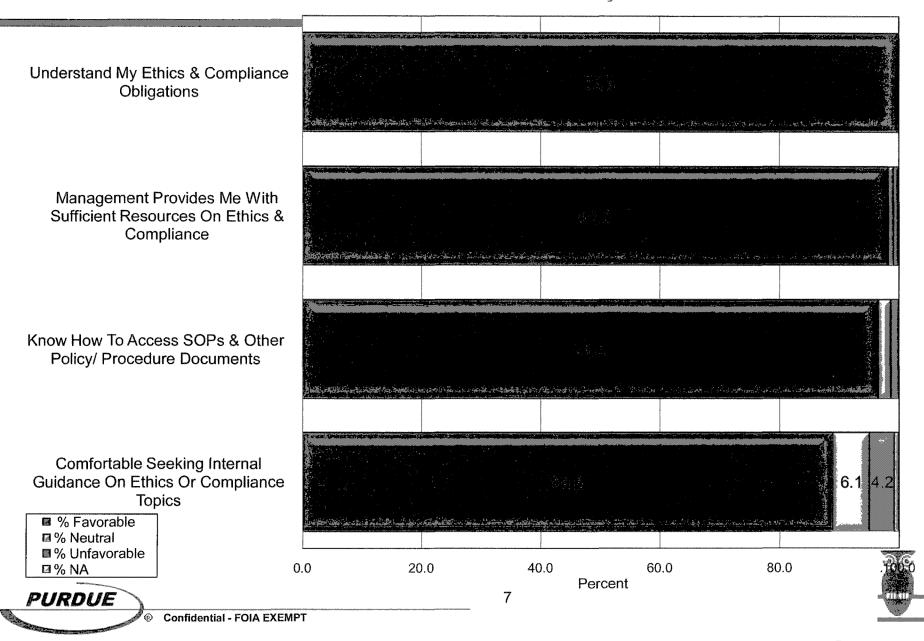
- The Compliance Charter is the policy document adopted by the Board of Directors to govern the compliance function
- It incorporates the Seven Elements of an "effective compliance program" under the Federal Sentencing Guidelines
- Purdue's compliance program has also been implemented pursuant to the OIG Compliance Program Guidance for Pharmaceutical Manufacturers, and is continually reviewed and updated in light of current standards and emerging developments.



HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY



### Purdue's 2010 Performance Culture Survey



# Purdue's Compliance Program, and the Seven Elements of an Effective Compliance Program





### **#1- Standards of Conduct & Procedures**

- Purdue's "Code of Business Ethics" is distributed to all employees of Purdue and associated US companies (including new hires)
  - All employees receive annual training
  - All employees must annually certify that they have received, read, understood and agree to abide by the Code
  - Code is on Purdue's internet and intranet web sites, and in hardcopy
- The Code articulates our ethics and compliance expectations and promotes employee awareness of responsibilities under current law and Purdue policies, including the obligation to report known or suspected violations
- Purdue has healthcare policies and procedures to promote employee awareness of the laws and standards applicable to interactions with healthcare professionals and other customers in the conduct of our business
- We also have an extensive system of departmental SOPs and WPDs



# #2 - Compliance Personnel & Oversight

- Purdue's Board of Directors is knowledgeable about the compliance program, and exercises oversight
  - Formal quarterly compliance presentations to the Board
  - Informal inquiries and issues discussed with Board
  - The Board provided the impetus for our Compliance Scorecard
- John Stewart exercises direct oversight of our compliance program, through regular meetings and interactions with Compliance Officer and others
- Purdue has a fully-dedicated compliance team under the leadership of the Vice President, Corporate Compliance, with operational responsibility, adequate resources, and appropriate authority





# #3 - Compliance Training

- All Employees receive training on Purdue's Code and on our Healthcare Law Compliance (HCLC) Policies, as noted above
- Sales and Marketing staff also participate in extensive live training sessions on HCLC Policies, including both didactic and scenariobased training, on the laws and regulations of the FDA, CMS, and other regulatory agencies.
- Purdue formally adopted the PhRMA Code on Interactions with Healthcare Professionals, and trains employees on the PhRMA Code
- All Purdue employees are also trained on Purdue's CIA
- All Purdue employees complete training on Adverse Event and Product Complaint Reporting.





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# Online Workplace Learning = OWL

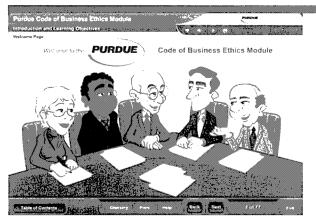


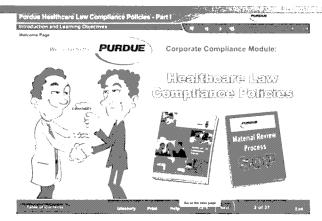
### OWL training includes:

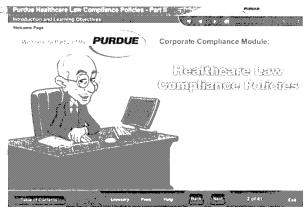
Purdue's Code of Business Ethics, Healthcare Law Compliance Policies,
Purdue's CIA, Adverse Events & Product Complaints, PhRMA Code,
Preventing Workplace Harassment, Antitrust, Careful Communication,
Ethical Leadership and Conflicts of Interest



# CIA-Required OWL Training Modules



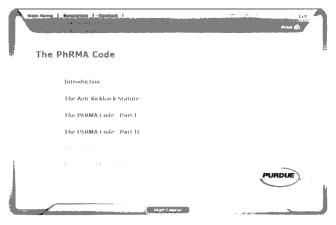


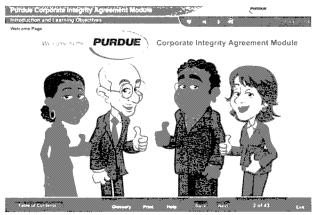


Code of Ethics
- 1 hour



Healthcare Law Compliance Policies
Part 2 – 1 hour





Purche Corporate Compliance Series

Production and tearing Objectives

We see this PURDUE Corporate Compliance Module:

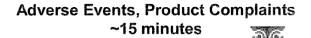
| Respecting /Adverse | Avenue

and Product Geomplaints

PhRMA Code
- 1 hour

Corporate Integrity Agreement

– 1 hour





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# Live Training Sessions – In House

- All new sales and marketing staff participate in live training sessions on HCLC Policies.
- These training sessions address laws and regulations of the FDA, CMS, and other regulatory agencies.
- Trainers are evaluated by participants

Level	<u>Attendees</u>	Content	<u> Training Dates</u>
100	New Sales Representatives	(1) HCLC Policies - standard slide	September 27 and 3
		deck and hand outfolder; (2)	October18-29,
		Scenarios	November8-19
150	Sales Representatives with 6-9	Snowball Fight	November 2-5
	months experience		
200	Sales Representatives with	Start with Snowball Fight, finish	November4
	approx. 24 months experience	with Gladiators	
300	Sales Representatives with 3+	Gladiators; last 15 minutes =	October14
	years experience	scenario developmentin teams	
400	Sales Representatives with ?+	Discussion and Gladiators	November15-19
	years experience		(cancelled)
500	District Field Trainers - 1 per	in Development	November3
	district		
600	New DMS, Part I	Phoenix/Compliance Training to	October18-19,
		include: Call Note Review and	November15-18
		Annotation, Field Contact	
		Reports, etc. (see below)	
610	New DMs, Part II	General Compliance Background;	
		FCRs, Ride Alongs, Call Note	
		Review, Call Annotations - Part II	
620	New DMs, Part III	Gladiators	
710	SMBA with focus on Coaching,	Currentissues in compliance	November8-11
	Hiring & Recruiting	world; keypoints, Gladiator	
720	SMBA with focus on	Currentissues in compliance	
	Communication Skills	world; keypoints, Gladiator	
730	SMBA with focus on Business	Currentissues in compliance	October 25-28
	Acumen	world; key points, Gladiator	

### Level 200 Sales Development Class Speaker Evaluations

November 2 - 6, 2009

Rating Scale:

Rating: 1 = Poor; 2 = Fair; 3 = Average; 4 = Good; 5 = Excellent

Comments are required for a rating of less than 3.

	Presentation/Speaker(s)	Rating for Speaker Delivery	Rating for Presentation Content	* Comments
_	Healthcare Compliance Maggie Feitz	4.8	4.8	Fun exercise, very real world info. Like snowball method to start activity

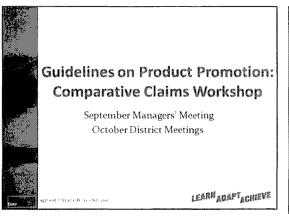


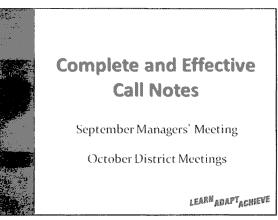
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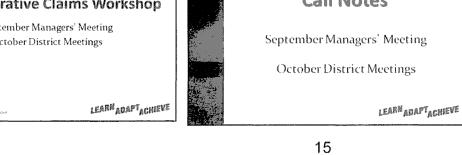
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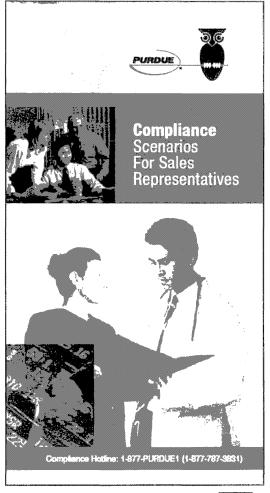
# Compliance Training In the Field

- Significant live compliance training is conducted in the home office and the field:
  - Regional and District Meetings
  - **Manager Meetings**
  - **National Sales Meetings**
  - Ride-alongs
- Training is also conducted by Sales Trainers, District and Regional Field Trainers, and by DMs and RDs. This helps to make Sales "owners" of compliance.











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**PURDUE** 

# The Axentis Enterprise System

Axentis System is Corporate Compliance's "Central Nervous System" for running the following functions:

- 1. Learning Management Manages and archives user training requirements
- 2. Incident Management
  - Corporate Compliance Investigations managed and archived
  - Disclosure Log production
- 3. Risk and Control Management
  - Documentation of Auditing and Monitoring activities

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# #4 – Disclosure Program

- Purdue maintains a 24 hour toll-free confidential Ethics and Compliance Hotline with "The Network," a third party vendor
  - Callers may remain anonymous
  - Every matter is logged into Axentis by us, no matter how important, and not just Hotline reports
  - Electronic files of every matter are maintained in Axentis
  - Disclosure Log reviewed at weekly team meetings, at Reportable Events Committee meetings, by Law department
- Purdue policy expressly prohibits retaliation or retribution against any employee for making a good faith report of suspected misconduct or improper behavior
- We regularly publicize our compliance program and our Disclosure
   Program through training, presentations, e-mails, posters, Purdue's newsletter, and other items

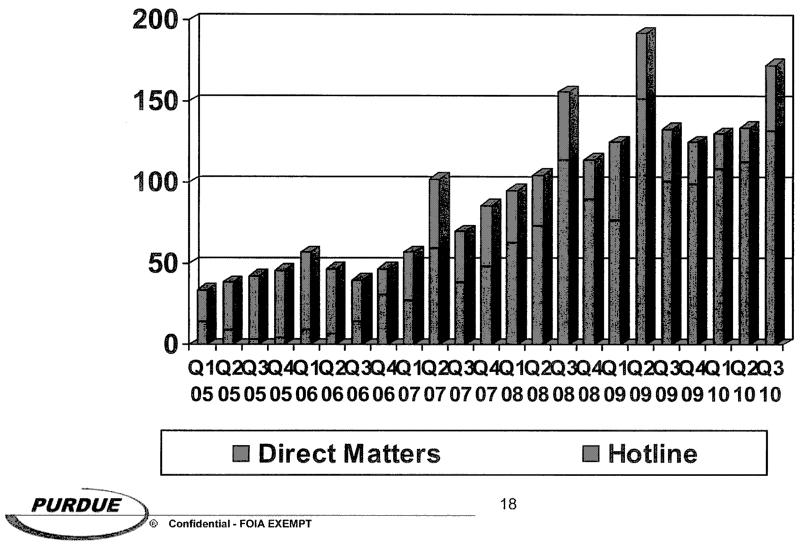
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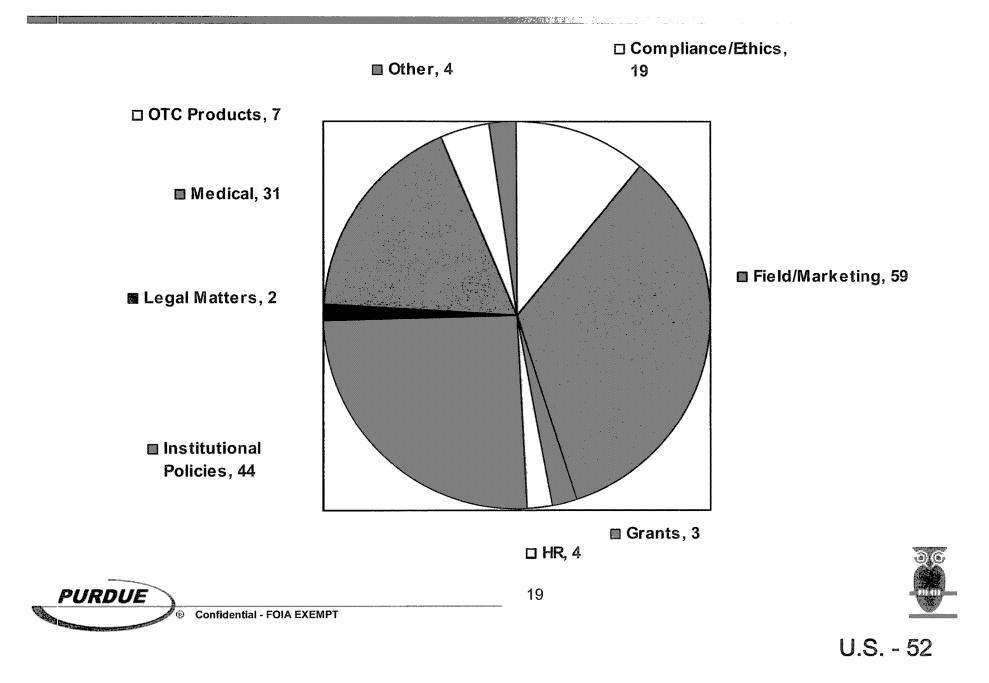
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# Matters, by Quarter (1Q05 – 3Q10)





# **3Q10 Compliance Matters**



# #5 - Auditing and Monitoring

- Corporate Compliance Audit Program
  - SOP for Corporate Compliance when performing audits
  - Includes procedures for audit planning, execution, reporting, distribution, follow-up, record keeping, and closure
- Audit schedule established at least annually by Corporate Compliance with input from stakeholders
- Based upon business needs, audits for cause may be executed as needed



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# Corporate Compliance Dashboard (excerpt)

Purdue Corporate Compliance Dashboard Analysis October 8, 2010

### **Table of Contents**

- \* Field Contact Report Regional Summary (page 2)
- \* Employee Training Summary (page 3)
- \* State Law Requirements by state (page 4)
- \* State Law Requirements by category (page 5)
- \* State Law Requirements by due date (page 6)
- \* Audits & Risk Assessments (page 7)

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### Field ContactReport Monitoring

Purdue

Corporate Compliance FCR Days - Reporting Period 4 Regional Summary July 31, 2010 - September 30, 2010

A B C=	A - B	D E=B+
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Region •	Reg Name	FCR Days Req	FCR Days Completed Toward Req	FCR Days Remaining	Additional FCR Days	Total FCR Days
⊎ <b>161</b>	North East	197	47	150	0	48
⊴162	Mid-Atlantic	264	82	182	0	82
- 163	South East	283	139	144	0	139
<b>∃164</b>	East Central	231	103	128	5	103
±165	North Central	221	89	132	0	90
⊎166	West Central	170	55	115	0	55
±167	South Central	274	108	166	0	108
⊴ 168	South West	154	63	92	1	64
<b>∃169</b>	North West	189	61	128	0	61
Grand Total		1,984	747	1,237	7	754

### Legend

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- (A) FCR Days Required: Equals the amount of field contact observation days required by the Corporate Integrity Agreement.
- (B) FCR Days Completed Toward Requirement: Equals the amount of field contact observation days completed toward the Corporate Integrity Agreement.

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- (C) FCR Days Remaining: Equals the amount of days remaining to meet the Corporate Integrity Agreement requirement.
- (D) Additional FCR Days: Equals the amount of field contact observation days above the Corporate Integrity Agreement requirement.
- (E) Total FCR Days: Equals the total amount of days spent by District Managers working with Sales Representatives.

<sup>\*</sup> Current Additional FCR Days driven by LOA - this will correct itself over the next few months.





# 2010 Audit Schedule Snapshot

Purdue Corporate Compliance Audits & Risk Assessments October 8, 2010

COM	PLETED	1					
#	Year		Description				
1		Audit	Healthcare Grants - Completed audit to confirm compliance to current operating procedures				
2	2009	Audit	Field Contact Reports - Completed audit to determine compliance to SOP requirements for District Managers. The audit included a review of metrics for expense submission and analysis of call note quality to assess appropriateness of compliance ratings of '1.' The results of this audit were several changes to items such as FCR approval, call no with additional coaching and workshops for RD's, DM's and Sales Representatives.				
3		Risk Assessment	Social Security # and Database Reconculation - Completed a risk assessment to determine the level of risk associated with social security names and numbers not matching				
4		Risk Assessment	Background Screenings - Completed a risk assessment on background checks being done for employee's pre and post employment.				
5	2009	Risk Assessment	In-Service sign in sheets - Completed a risk assessment on HCP in-service sign in sheets. The lack of consistency in compliance to 5OPs makes this assessment a media recent sales bulletin to reinforce company expectations, we anticipate seeing improvement to the 5OPs and plan to conduct an audit during the first quarter of 2010.				
6	2009	Risk Assessment	Savings Card Distribution & Unlization - The purpose of the assessment was to review Oxy Contin savings card utilization and distribution. The initial analysis revealed the had almost twice the number of redemptions. This information was shared with Legal and the Internal Audit function. We will assess again at a later date in the future				
сом	PLETED	ı					
#	Year		Description				
1	2010	Audit	Contracts Database - To review the database for Legal to assess input accuracy. Completed Q1 of 2010				
2	2010	Audit	FCR Analysis - Based on our original audit and subsequent changes to our policies and procedures, we would like to revisit in order to measure the anticipated improvement areas. This audit was completed in Q3 of 2010.				
1	2010	Risk Assessment	HIPAA Information - A request was made by Finance to review the company's HIPAA procedures. The main concern centers around protecting the health information of concern stream groups who have access to background screens, medical information and other highly confidential data. What safeguards are in place to protect this information concern stream groups who have access to background screens, medical information and other highly confidential data. What safeguards are in place to protect this information.				
IN-PR	OGRES Year		Description				
1		Audit	In-service Sign Sheets – Maggie, based on the memo that was sent out in September and our initial review, we would like to revisit this risk assessment during the 2 <sup>nd</sup> or 3'' measure the expected improvement. Annicipated completion – Q4 of 2010				
2	2010	0 Risk Assessment Sales Force/Manager Training - A request was made by Sales Management to review some of the non-compliance training sessions. The goal of this review are approved, not revised from the approved version, the trainer stays on-topic, etc.					
PROJ	ECTED						
#	Year		Description				
1		Audit Audit	ADD Audit - To review current policies, procedures, and SOPs  Consulting Agreement - To review and analyze the current Udell consultancy agreement				
3	2010	Audit	HR - To review the Human Resource Information Management System. Before any work begins, Bert will review with David Long first				
1	2010	Risk Assessment	CSA Audit Reports - A request was made by Finance to review the CSA audit reports. The main concern centers around tracking and accounting for controlled substances				
2	2010	Risk Assessment	HCP Contracts - A request was made by finance to review HCP contracts. The main question was which HCPs are Purdue paying and do we have any contracts with them?				
3	2010	Risk Assessment	Sr. Office & Board Expense Reports - A request was made by Finance to review Sr. Officer and Board expense reports. The main concern centered around checking for an meals/entertainment/gift spend used on HCPs.				
4	2010	Risk Assessment	District Meeting - A request was made by Sales Management to review a District Meeting. The goal would be to assure that content and materials are being delivered as plants.				
5	2010	Risk Assessment	IPAP Program - A request was made by Finance to review the IPAP program. The main concern centered around the utilization of the program.				
б	2010	Risk Assessment	Sampling - A request was made by Finance to review the sampling program. The main concern centers around the current procedures of the program and the level of risk a distributing product for free				

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# **Auditing and Monitoring**

### **Phoenix Call Note Review and Monitoring**

- Since January 2006, Sales Representatives have been required to enter free text call notes in the Phoenix Territory Management system
- District Managers are required to review call notes of all representatives in their district
- New monitoring and oversight features are implemented on an on-going basis
  - Call note Word Searches, regularly updated
  - Call note annotations, reviewed regularly





# **Compliance Section of PMP Forms**

Compliance to Policies and Procedures		For OIG Demonstration only
Legal Guidelines for Product Promotion	5	For OIG Demonstration only
Healthcare Law Compliance (HCLC) Policies	5	For OIG Demonstration only
Code of Business Ethics	5	For OIG Demonstration only
Indicators of Possible Diversion	5	For OIG Demonstration only
Expense Reporting/Attribution	5	For OIG Demonstration only
Call Reporting	1	For OIG Demonstration only
AE Reporting/Product Complaints	5	For OIG Demonstration only
Reports Of Concern (ROCs)	5	For OIG Demonstration only
Sampling (PDMA)	5	For OIG Demonstration only
Professional Conduct	5	For OIG Demonstration only
Requests for Off-Label Information	5	For OIG Demonstration only
Grants	5	For OIG Demonstration only





### **Exit Questionnaire Process**

- Process initiated January 2006 together with Human Resources
  - All personnel who terminate employment are provided a Corporate Compliance Exit Interview Questionnaire to complete; may be returned directly to Compliance
  - Signed original Questionnaires are received, reviewed, and maintained by Corporate Compliance





# #6 - Screening / Discipline

Written procedures for background screening by Human Resources

### New Hires

- Checked against the DHHS database by name and social security number; any matches are brought to the attention of the VP of Human Resources and the General Counsel's office
- Applicant certification page verifies new hire has not been debarred under the Federal Food, Drug and Cosmetic Act and has not been convicted of any violation related to the FDCA within the preceding 5 years

### Existing Employees

- DHHS Exclusions Database check performed annually
- Employees are required to report criminal conduct, exclusion, debarment or suspension, or notice thereof under our Code





# Screening / Discipline

- Sales "Discipline Committee" meetings held regularly
  - Members include Compliance, Law, HR, and Sales Management
  - Review open issues, determine discipline, maintain records of decisions
- Confidential discipline database maintained by Law Department





### #7 – Investigation of Violations & Remediation

# PURDUE PHARMA L.P. and ASSOCIATED US COMPANIES PURDUE PHARMA L.P. STAMFORD, CONNECTICUT STANDARD OPERATING PROCEDURE

SOP NUM.: CC-SOP-000007

TITLE: CORPORATE COMPLIANCE INVESTIGATIONS

SUPERCEDES: CC-WPD-000002 v.1.0

### PURPOSE

Purdue has a long-standing commitment to conduct its business in compliance with applicable laws and regulations and in accordance with the highest ethical standards. Consistent with this commitment, Purdue will promptly and thoroughly investigate potential violations of law, regulation or Company policy pursuant to the procedures established below.

This Standard Operating Procedure (SOP) sets forth the guidelines applicable to the conduct of Investigations conducted by Corporate Compliance members.

### 2. SCOPE

These guidelines must be followed by members of Corporate Compliance who receive notification of alleged misconduct or wrongful behavior, as well as by Purdue Employees, including agents, who assist Corporate Compliance in conducting an Investigation.

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# Ongoing Investigation Reported to OIG

### Ryzolt Matter – initial notice in 5/13/2010 letter

- During routine monthly reviews of call notes based on a number of search terms, discovered references by two sales representatives that appeared to discuss the use of Ryzolt tablets for treatment of "mild pain" or "mild to moderate pain." This message is contrary to the training and continued guidance provided to representatives regarding the indication of this product.
- Reviewed full year of call notes since launch 496 referenced the word "mild," and 201 (51 reps) required full investigation.
- Extensive remedial actions implemented, including bulletins to the field, live compliance training at June Regional meetings, three hour special meeting of all sales managers, as well as discipline.



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### Investigation Reported to OIG

### Comparative Claims matter – initial notice in 8/30/2010 letter

- Routine review of call notes revealed references that suggested potential comparative claims of superiority of Purdue products relative to competitors. Conducted broader review of all call notes entered after training on comparative claims in June 2009. A total of 75 potentially problematic notes were identified. Interviews were held with responsible sales representatives, and district managers who had reviewed, but not commented on those call notes.
- Follow up discipline included: termination of one representative for multiple compliance violations, probation for a second representative, written warning letters for an additional 16 representatives. One manager received a written warning letter, and a second was provided with verbal coaching.
- Additional procedures have been put in place to ensure that any training on promotional issues that a representative misses will be provided when the representative returns from leave (or joins the company if a new employee).
- Will continue to monitor call notes for this issue.



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### "Reportable Event" to OIG

### OxyContin Visual Aid Matter—initial notice in 12/23/08 Letter

- Discovered in the course of regular monthly word-search review of call note database. This matter involved call notes suggesting improper use of an OxyContin visual aid, to suggest there was less potential for diversion and abuse given the lesser number of pills in a month's worth of 60 OxyContin tablets versus 240 tablets for an immediate release dosage form of opioid. The intent of the visual aid was to communicate patient compliance and convenience, and certainly not meant to have any connection with lower abuse or diversion potential.
- Thoroughly investigated, remediated, and closed no OIG action





### Reported to OIG

### Promotion Monitoring Matter – 4/16/09 email notice

- Investigation revealed that a few District Managers had fallen short of expectations for: reviews of call notes; time spent in field doing ridealongs with representatives; routine administrative activities; accurate and complete documentation (calendars, FCRs, etc.). Our 6/18/09 letter laid out the facts and corrective actions taken, including discipline, and also with respect to a shortfall in the required number of days of representative field observation by DMs during CIA year 1.
- Closed November 2009 no action





### Significant Matters Reported to OIG

### OxyContin Savings Card Matter 3/19/09 letter

- Purdue discovered and reported the existence of representative call notes with references to savings cards and federal healthcare programs. The issue concerned potential use of the card by Medicare Part D beneficiaries who may have paid cash for certain prescriptions filled during the period they are in the coverage gap (commonly referred to as the "Donut Hole"). Use of the savings cards is explicitly prohibited by the terms of the cards themselves. Thoroughly investigated by outside counsel, with no evidence of any improper use.
- Purdue implemented new safeguards a savings card activation process (like a credit card), and a pharmacist verification process when prescriptions are filled
- Closed November 2009 no OIG action





### Healthcare Grant Review Committee

### Charter

Responsible for collecting, evaluating, providing disposition and reporting of all grant requests received by Purdue and donations from Purdue that relate to educational, scientific and other initiatives that contribute to improved healthcare. Such requests may include healthcare-related:

- **Educational Grants**
- Scholarships and awards
- **Advocacy initiatives**
- Charitable financial contributions
- **Product donations**
- In-kind contributions

### Members

- Executive Director, HC Education & Liaison Programs (V)
- Associate Medical Director, Medical Research (V)
- Senior Manager, Corporate Compliance (V)
- V=voting member
- **Executive Director, Healthcare Alliance Development (V)**
- **Associate Director, Medical Education**
- Coordinator(s) and Manager, Medical Education
- Senior Assistant General Counsel

### Decision rights

- Follows relevant HGRC SOP
- **Decides grant disposition** 
  - Full funding/support
  - Partial funding/support
  - **Decline funding/support**
  - Defer (for internal or external information, or other reasons)
- Distributes HGRC reports and informs Executive Committee and all relevant functions
- Meetings
- Meetings occur as designated by the Chairperson (usually weekly)
- Two weeks prior to each meeting a grant review packet is circulated to committee members
- A meeting decision report is communicated within 3 days to all members and internal interested parties and posted on SharePoint, along with monthly and quarterly reports
- A quarterly report for all Healthcare Grants/Donations is provided to the Finance Department



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### Independent Review Organization

### **Transaction Reviews in Years 1-3**

- First Reporting Period
  - Focus Inquiry Monitoring 6 Findings
  - Promotion Monitoring Program 3 Findings
- Second Reporting Period
  - Focus Inquiry Monitoring 6 Findings
  - Promotion Monitoring Program 3 Findings
    - All issues from the first two Reporting Periods have been addressed
- Third Reporting Period
  - Focus Inquiry Monitoring 2 Findings
  - Promotion Monitoring Program 1 Finding
  - Two of the findings have been addressed, with the final action item due January 1, 2011

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# Independent Review Organization

### Systems Reviews - Year 2

- Nine systems listed in Appendix B of Purdue's CIA
- Most findings were minor in nature and addressed by updating procedural controls
- Most significant issues found by IRO were with Purdue's Material Review Process
  - Purdue handled as a critical issue
  - A project was initiated in July 2009
    - Replace Purdue's paper-based Material Review process
    - Identify process steps needing improvement
    - Select an electronic Material Review system and implement
  - Purdue's electronic Material Review system went live on 08/02/2010





# We work together to produce results

Through the efforts of many of Purdue's employees, we work together and share relevant compliance information and feedback in many ways throughout the year to drive good results:

- Corporate Compliance Council
- Sales and Marketing Compliance Committee
- Vice Presidents' Compliance Council
- R&D Compliance
- Administrative Area Compliance Committee
- Grant Review Committees
- Reportable Events Committee
- Discipline Committee
- Quality Steering & Technical Operations Committees
- Executive Committee and Board of Directors





### **OIG Close-Out Meetings**

- OIG Monitor Keisha Thompson: "A busy couple of days"
- Ten employee interviews
  - Employees randomly selected by OIG
  - OIG stated that employees "consistently demonstrated compliance knowledge and awareness...a very good sign"
- OIG recognized Purdue's emphasis on compliance, training, adequate compliance resources, IT systems – "positive"
- Pre-CIA vs. post-CIA area of greatest innovation- use of data to connect with the field – "good progress"





# **OIG Close-Out Meetings**

- Likely Areas for work (pending receipt of written report from OIG)
  - Material Review (action plan: new electronic system implemented 8/10)
  - Fee-for service arrangements (action plan: focus on process for new speaker programs)
  - Risk Assessment process (action plan: implementing company-wide vs. business unit assessments)
- Take-aways:
  - Complementary and positive site visit, many areas of progress and strength cited, some areas for improvement expected
  - OIG wants all pharma companies to look to current CIAs for guidance on their thinking with respect to compliance practices





# Other 3Q10 Compliance Highlights

### New CIAs in the 3rd Quarter

0	Allergan	\$600	Botox off label promotion
	Novartis	422	Trileptal (and other) off-label promotion
•	Forest	313	Celexa off-label promotion
•	Elan	203	Zonegran off-label promotion

(over \$3 billion since January, 2010)

### October 19-22 Pharmaceutical compliance Congress

- "Theme" Park doctrine and prosecution of individuals
- OIG's Sr. Counsel Mary Riordan
  - Announced publication of new OIG guidance on exercise of permissive exclusion of owners, officers, and managers of sanctioned entities- if knew or should have known of bad conduct, "presumption in favor of exclusion"
  - · "Predicts" increasing numbers of cases against individuals, and
  - Continued large numbers of cases against pharma companies
  - "Recommends" adoption of Risk Assessment and Mitigation Programs



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